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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,503	12/28/2001	Qingsheng Zhu	279.132US2	2027
21186	7590	03/03/2004		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER EVANISKO, GEORGE ROBERT	
			ART UNIT 3762	PAPER NUMBER 4
DATE MAILED: 03/03/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,503

Applicant(s)

ZHU ET AL.

Examiner

George R Evanisko

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3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) 9, 10, 12-15 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 11, 16, 17, 22, 23, 27, 29 is/are rejected.
- 7) ☒ Claim(s) 5-7 and 24-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Claims 9, 10, 12-15, and 28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected embodiments, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 3. In addition, although the applicant states claim 10 reads on the elected embodiment, it has been withdrawn since it depends on non-elected claim 9.

Information Disclosure Statement

The information disclosure statement filed 12/28/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein that has been lined through has not been considered. Although the applicant states all the references were in the parent case, the lined through references were not cited or provided in the parent case.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 16 and 17 are vague and conflict with claim 1. Claims 16 and 17 state that “the at least one electrode” includes a first electrode and a second electrode, with the first electrode located at the distal end. Claim 1 states that the “at least one electrode” is located entirely in the intermediate portion of the lead body between the proximal and distal ends. Therefore the claims conflict and it is unclear how many electrodes are being claimed and where the electrodes are located. In addition, it is unclear if both the first and second electrodes are coupled to the one conductor coil or separate coils and are both 1.2 sq. mm. The claims could not be further examined in view of the prior art. Also, “is cathodic” and “is anodic” in polarity are vague since no pulse generator has been provided to place a positive or negative voltage on the electrodes. It is suggested to use “adapted to be cathodic in polarity”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Brownlee (5127403). Brownlee states in column 9 that the electrodes can be 1 sq mm and shows the electrodes flush with the lead body.

Claims 22 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Hirschberg. Hirschberg states in column 3 that the ring electrodes can have a surface area of 1 sq mm and shows the ring electrodes flush with the lead body.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 8, 11, 23, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brownlee (or Hirschberg).

Brownlee (or Hirschberg) discloses the claimed invention except for the conductor being a coil (claim 1), the sleeve being partially masked by the lead body (claim 3), and the lead having a drug collar or porous member next to the electrode (claims 4, 8, 23, and 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Brownlee (or Hirschberg), with the conductor being a coil, the sleeve being partially masked by the lead body, and the lead having a drug collar or porous member next to the electrode since it was known in the art that implantable leads use: the conductor being a coil to provide flexibility and/or stiffness to the lead; the sleeve being partially masked by the lead

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body to control the surface area of the electrode and allow the electrode to be firmly attached to the lead body; and the lead having a drug collar or porous member next to the electrode to allow the drug to flow from the collar/member to treat the heart where the electrode irritates the heart and/or to allow tissue ingrowth into the collar/porous member.

Allowable Subject Matter

Claims 5, 6, 7, and 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GRE
February 28, 2004

GEORGE R. EVANISKO
PRIMARY EXAMINER

2/28/4